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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/163,089	09/29/1998	IAN F. C. MCKENZIE	4102-1	9586

22442 7590 07/29/2002

SHERIDAN ROSS PC
1560 BROADWAY
SUITE 1200
DENVER, CO 80202

EXAMINER

ZEMAN, ROBERT A

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 07/29/2002

25

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/163,089

Applicant(s)

MCKENZIE ET AL.

Examiner

Robert A Zeman

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE _____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 08 April 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 3-17, 19-21, 24-26, 38 and 70 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-17,19-21,24-26,38 and 70 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 25.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Art Unit: 1645

DETAILED ACTION

The amendment and response filed on 4-8-2002 is acknowledged. Claims 1, 8, 9, 15, 17, 20, 24, 38 and 70 have been amended. Claims 2, 22, 27-37, 39-46 and 48-51 have been canceled. Claims 1, 3-17, 19-21, 24-26, 38 and 70 are pending and currently under examination.

Information Disclosure Statement

The IDS filed on 4-15-2002 is acknowledged. An initialed copy is enclosed. It should be noted that all references listed were not considered. Only those references that were available were considered. The remaining references will be considered as soon as they become available.

Claim Rejections Withdrawn

The rejection of claims 1, 20 and 70 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the use of the term "immunoregulatory" is withdrawn in light of the amendment thereto.

The rejection of claims 1, 38 and 70 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite as they are drawn, in part, to a non-elected invention is withdrawn in light of the amendment thereto.

The rejection of claim 8 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the use of the term "contacted" is withdrawn in light of the amendment thereto.

The rejection of claim 9 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the use the term "capable of" is withdrawn in light of the amendment thereto and Applicant's arguments. It should be noted that use of the term "capable of" with regard to

Art Unit: 1645

the claimed cells is superfluous since only cells with the ability to express mannose receptors would respond to an inducer.

The rejection of claim 15 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the use of the term “~~the~~ repeated subunits” is withdrawn in light of the amendment thereto.

The rejection of claim 17 under 35 U.S.C. 112, second paragraph, for reciting improper Markush language is withdrawn in light of the amendment thereto.

The rejection of claim 20 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the use the term “can be” is withdrawn in light of the amendment thereto.

The rejection of claim 20 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the use of the term “antigen delivery medium” is withdrawn in light of the amendment thereto.

The rejection of claim 24 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the use of the term “in the presence of” is withdrawn in light of the amendment thereto.

The rejection of claim 24 under 35 U.S.C. 112, second paragraph, as not further limiting the claim on which it depends is withdrawn in light of the amendment thereto.

Claim Rejections Maintained

35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

Art Unit: 1645

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The rejection of claims 1, 3-17, 19-21, 24-46, 38 and 70 under 35 USC 112, first paragraph, because the specification, while being enabling for immunoregulatory compositions comprising mannose receptor bearing cells, and a conjugate comprising MUC1 (antigen) and a carbohydrate polymer comprising mannose, wherein said carbohydrate polymer is a fully oxidized carbohydrate polymer comprising free aldehydes, does not reasonably provide enablement for immunoregulatory compositions comprising mannose receptor bearing cells, and a conjugate comprising **any** antigen and a carbohydrate polymer comprising mannose, wherein said carbohydrate polymer is a fully oxidized carbohydrate polymer comprising free aldehydes is maintained for reasons of record. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected to make and use the invention commensurate in scope with these claims.

Applicant argues:

1. The specification lists other antigens that could be used in the claimed compositions for the elicitation of a cellular immune response.

Applicant's arguments have been fully considered and deemed unpersuasive. None of the other antigens listed in the Specification are shown to elicit any type of immune response in the claimed compositions. As set forth previously, it is entirely unclear how other antigens will behave in vivo when used in the claimed compositions, absent any evidence.

Art Unit: 1645

Applicant supplied two later published articles in support of the aforementioned arguments however, these papers do not address compositions falling within the metes and bounds of the claims. The Stambas 2002(a) article administers a conjugate of an antigen with oxidized mannan, however, the administered composition does not comprise mannose receptor bearing cells. Similarly, the Stambas 2002(b) article does not disclose results using the claimed compositions. The administered compositions in Stambas 2002(b) do not comprise mannose receptor bearing cells. Therefore, these articles are deemed unpersuasive.

Applicant has also provided a declaration of Dr. Pietersz, under 37 CFR 1.132, in support of the aforementioned arguments. This declaration is deemed unpersuasive as it does not use compositions that fall within the scope of the instant claims. The claims require mannose receptor bearing cells. The compositions used in the experiments described in the declaration appear to only comprise the conjugate of the antigen and the carbohydrate polymer. Consequently, said declaration is deemed unpersuasive.

35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various

Art Unit: 1645

claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The rejection of claims 1, 3-17, 19-21, 24-26, 38 and 70 under 35 U.S.C. 103(a) as being unpatentable over Apostolopoulos et al. (PNAS Vol. 92, pages 10128-10132) in view of Koning et al. (WO 98/13378) is maintained for reasons of record.

Applicant argues:

1. The parent application provides description of the claimed invention, and therefore cannot be denied priority.

Applicant provided pages from the parent specification in support of that assertion. These arguments and evidence are unpersuasive, as they do not disclose compositions falling within the claims. The parent specification fails to disclose compositions which comprise the mannose receptor bearing cells, along with the conjugate of the antigen and the carbohydrate polymer. As such, the parent application does not disclose or enable the claimed composition, and priority to said application is denied, and the art applies as set forth previously.

New Grounds of Rejection

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

Art Unit: 1645

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Said claim recites the phrase "induce mannose receptors". It is unclear what is meant by said phrase. Induce the receptors to perform what function? As written, it is impossible to determine the metes and bounds of the claimed invention.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Art Unit: 1645

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A Zeman whose telephone number is (703) 308-7991. The examiner can normally be reached on M-Th 7:30 am - 5:00 pm and Alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful Donna Wortman, Primary Examiner, can be reached on (703) 308-1032. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



DONNA WORTMAN
PRIMARY EXAMINER

Robert A. Zeman
July 26, 2002